

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : NALDINI, et al.

U.S. Serial No. : Not Yet Known, corresponding to  
International Application No.  
PCT/IT04/000227, filed April 21, 2004,  
claiming the benefit of U.S. Serial No.  
60/465,080, filed April 24, 2003

Filed : Herewith

For : LENTIVIRAL VECTORS CARRYING SYNTHETIC BI-  
DIRECTIONAL PROMOTERS AND USES THEREOF

Law Offices of Albert Wai-Kit Chan, LLC  
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October 21, 2005

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450  
Mail Stop Patent Application

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, Applicants would like to direct the Examiner's attention to the following references which are listed below and on Forms PTO/SB/08A and PTO/SB/08B (which are attached hereto as **Exhibit A**), and each individual reference further attached as **Exhibits 1** through 7.

1. PCT International Search Report for NALDINI, et al., Int'l Application No. PCT/IT04/000227, Filed April 21, 2004, Dated October 12, 2004 [**Exhibit 1**]
2. YU, et al., "Lentiviral Vectors with Two Independent Internal Promoters Transfer High-Level Expression of Multiple Transgenes to Human Hematopoietic Stem-Progenitor

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Cells", Molecular Therapy, Vol. 7, No. 6, Pages 827-838  
(2003) [Exhibit 2]

3. FUX, Cornelia and FUSSENEGGER Martin "Bidirectional Expression Units Enable Streptogramin-Adjustable Gene Expression in Mammalian Cells", Biotechnology and Bioengineering, Vol. 83, No. 5, Pages 618-625 (2003) [Exhibit 3]
4. FUX, Cornelia and FUSSENEGGER Martin "Toward Higher Order Control Modalities in Mammalian Cells-Independent Adjustment of Two Different Gene Activities", Biotechnol. Prog, Vol. 19, Pages 109-120 (2003) [Exhibit 4]
5. UNSINGER, et al., "Retroviral Vectors for the Transduction of Autoregulated Bidirectional Expression Cassettes", Molecular Therapy, Vol. 4, No. 5, Pages 484-489 (2001) [Exhibit 5]
6. UNSINGER, et al., "Stable and strictly controlled expression of LTR-flanked autoregulated expression cassettes upon adenoviral transfer", Biochemical and Biophysical Research Communications, Vol. 319, Pages 879-887 (2004) [Exhibit 6]
7. International Publication Number WO 2003/087294 A2 for Universitätsklinikum Hamburg-Eppendorf, Published April 8, 2003, "Recombining Viral Vectors for the Tetracycline-Regulated Expression of Genes" [Exhibit 7]
8. U.S. Patent No. 6,630,324 B1 for BARSKI, et al., Published October 7, 2003 "Aldehyde Reductase Bidirectional Promoter and its use".

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A copy of the above U.S. Patent is on file at the USPTO; therefore, a copy will not be provided. Applicant's attorney's office may be contacted in the event that the Examiner would like a copy of the reference.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

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PTO/SB/08B (02-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number	Not Yet Known
		Filing Date	Herewith
		First Named Inventor	Luigi NALDINI
		Art Unit	Not Yet Known
		Examiner Name	Not Yet Known
Sheet 1	of 2	Attorney Docket Number	1130-PCT-US

OTHER PRIOR ART—NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1	PCT International Search Report for NALDINI, et al., Int'l Application No. PCT/IT04/000227, Filed April 21, 2004, Dated October 12, 2004	
	2	YU, et al., "Lentiviral Vectors with Two Independent Internal Promoters Transfer High-Level Expression of Multiple Transgenes to Human Hematopoietic Stem-Progenitor Cells", Molecular Therapy, Vol. 7, No. 6, Pages 827-838 (2003)	
	3	FUX, Cornelia and FUSSENEGGER Martin "Bidirectional Expression Units Enable Streptogramin-Adjustable Gene Expression in Mammalian Cells", Biotechnology and Bioengineering, Vol. 83, No. 5, Pages 618-625 (2003)	
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	6	UNSINGER, et al., "Stable and strictly controlled expression of LTR-flanked autoregulated expression cassettes upon adenoviral transfer", Biochemical and Biophysical Research Communications, Vol. 319, Pages 879-887 (2004)	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

**(Use as many sheets as necessary)**

Sheet	2	of	2
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**Complete if Known**

Application Number	Not Yet Known
Filing Date	Herewith
First Named Inventor	Luigi NALDINI
Art Unit	Not Yet Known
Examiner Name	Not Yet Known
Attorney Docket Number	1130-PCT_US

## U. S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

Examiner Signature		Date Considered	
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